PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61H 9/00 — A1

(11) International Publication Number: WO 95/01770

(43) International Publication Date: 19 January 1995 (19.01.95)

(21) International Application Number: PCT/US94/07577

(22) International Filing Date: 6 July 1994 (06.07.94)

(30) Priority Data:
088,895 8 July 1993 (08.07.93) US

(71) Applicant: AIRCAST, INCORPORATED [US/US]; 92 River Road, Summit, NJ 07902-0709 (US).

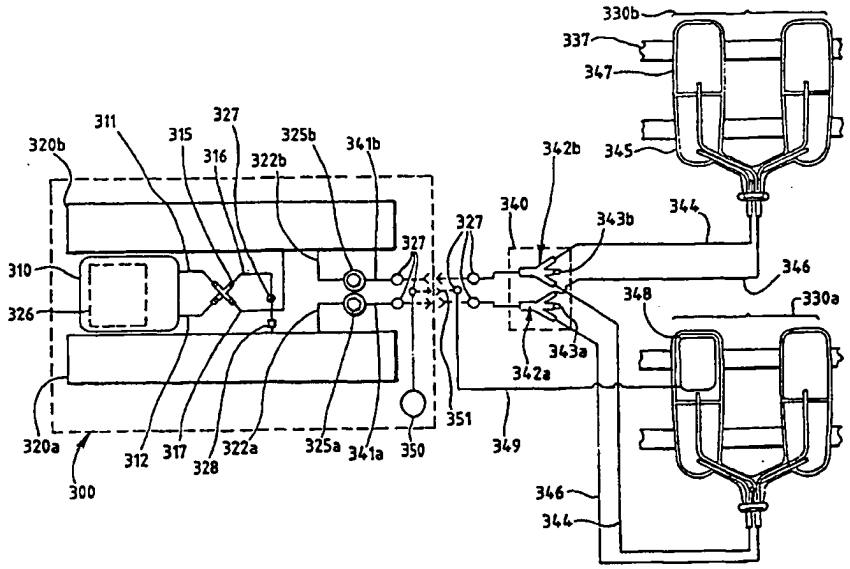
(72) Inventors: JOHNSON, Glenn, W., Jr.; 10 Friar Tuck Circle, Summit, NJ 07901 (US). McVICKER, Henry, J.; Apartment 9H Heritage Drive, Chatham, NJ 07928 (US). HARGRAVE, David, C.; 9 Overlook Road, Chatham, NJ 07928-2704 (US).

(74) Agents: SANDLER, Ronald, A. et al.; Jones, Day, Reavis & Pogue, 77 West Wacker Drive, Chicago, IL 60601-1692 (US).

(81) Designated States: AU, CA, ES, FI, JP, NO, NZ, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
With amended claims.

(54) Title: METHOD AND APPARATUS FOR PROVIDING THERAPEUTIC INTERMITTENT COMPRESSION FOR REDUCING RISK OF DVT



(57) Abstract

A method and apparatus are disclosed for providing therapeutic intermittent pneumatic pressure to a body portion. An air reservoir (320) receives a substantially steady flow of pressurized air for a pump (310). Pressure is applied as a rapid pulse from the reservoir (320) to a cuff means (330A, 330B) in contact with the body portion so as to promote acceleration of venous blood flow in the body portion. In a preferred embodiment, the pneumatic pressure is applied in a graduated manner and/or sequentially distally to proximally along the body portion. A simplified carrying arrangement (300) is provided for the system.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria
AU	Australia
BB	Barbados
BE	Belgium
BF	Burkina Faso
BG	Bulgaria
BJ	Benin
BR	Brazil
BY	Belarus
CA	Canada
CF	Central African Republic
CG	Congo
CH	Switzerland
CI	Côte d'Ivoire
CM	Cameroon
CN	China
CS	Czechoslovakia
CZ	Czech Republic
DE	Germany
DK	Denmark
ES	Spain
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
GE	Georgia
GN	Guinea
GR	Greece
HU	Hungary
IE	Ireland
IT	Italy
JP	Japan
KE	Kenya
KG	Kyrgystan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
KZ	Kazakhstan
LI	Liechtenstein
LK	Sri Lanka
LU	Luxembourg
LV	Latvia
MC	Monaco
MD	Republic of Moldova
MG	Madagascar
ML	Mali
MN	Mongolia
MR	Mauritania
MW	Malawi
NE	Niger
NL	Netherlands
NO	Norway
NZ	New Zealand
PL	Poland
PT	Portugal
RO	Romania
RU	Russian Federation
SD	Sudan
SE	Sweden
SI	Slovenia
SK	Slovakia
SN	Senegal
TD	Chad
TG	Togo
TJ	Tajikistan
TT	Trinidad and Tobago
UA	Ukraine
US	United States of America
UZ	Uzbekistan
VN	Viet Nam

METHOD AND APPARATUS FOR PROVIDING THERAPEUTIC INTERMITTENT COMPRESSION FOR REDUCING RISK OF DVT

BACKGROUND OF THE INVENTION

TECHNICAL FIELD

The present invention relates in general to improvements in a therapeutic system for producing automatic intermittent compression to minimize or prevent deep vein thrombosis (DVT). More specifically, it relates to a system including a source of intermittent pressure and one or more pressurizable chambers attached to a human leg for providing treatment by applying intermittent compression to the leg by means of the chambers to accelerate the flow of venous blood and thereby minimize the risk of or prevent DVT. In a preferred embodiment, two or more chambers are used and the intermittent compression may be graduated along the body portion to which it is applied, and may also be applied sequentially to the two or more chambers.

BACKGROUND ART

Therapeutic intermittent pneumatic compression of the leg for the prevention of DVT after surgery has been used for more than twenty years, and a variety of devices, many patented, have been developed for its application. Even with these devices, the incidence of DVT remains relatively high and the use of

existing equipment is somewhat limited because of its high cost and patient discomfort. A clear and well recognized need exists for a system that is more effective, less costly, and more comfortable for the patient.

Intermittent pneumatic compression is the technique of cyclically compressing the limb with air pressure so as to enhance circulation of blood. It has been shown effective in reducing the risk of thrombosis after surgery and for treatment of vascular deficiencies. The pressure is applied from a source of compressed air by a control mechanism that intermittently inflates a cuff enveloping the arm or leg. The period of compression is typically short, ten seconds or so, and the interval between pulses about a minute. Studies having shown this to be the time required for the veins to refill after being emptied by the short pulse of compression.

Studies have also shown that the optimal amount of compression is in the range of 35 to 45 mm hg, and that the velocity of the venous flow during the period of compression is proportional to the rate at which the pressure rises. For example, a pulse that rises to 35mm hg in six seconds accelerates venous velocity by several times that of a pulse that requires 30 seconds. Because it is this acceleration of venous flow that is believed to reduce the risk of pooling and clotting of blood in the deep veins, the rate of

pressure rise is a critical variable of effectiveness in reducing the risk of or preventing DVT. Cost and comfort are also variables, because the more expensive and less comfortable devices are less likely to be used.

It has been shown that intermittent pneumatic compression (IPC) is more effective in preventing DVT when there is a higher velocity of venous flow during the period of compression. Graduated intermittent pneumatic compression of fluid chambers applied to an injured body portion is well known and its efficacy is broadly accepted by the medical profession. With graduated IPC, pressures of different magnitude are applied to different regions of the body portion being treated. Most typically higher pressure are applied to the distal regions and lower pressures are applied to the proximal regions. IPC may also be applied sequentially, with the distal region of the treated limb being pressurized slightly before the proximal region. It also has been reported that a combination of sequential and graduated compression may be the most effective in providing accelerated venous flow.

Roberts, et al., "Hemodynamics of the Lower Limb in Man," Brit. J. Surg., Vol. 59, No. 3, pp. 223-226, March 1972, reports that intermittent pressure applied with an inflatable plastic splint causes an increase in venous peak flow directly proportional to the rate of pressure application, being maximal at

about 10 mmHg per second, with the maximum being reached when the pressure is applied at 1 minute intervals.

Nicolaides, et al., "Intermittent sequential pneumatic compression of the legs in the prevention of venous stasis and postoperative deep venous thrombosis," Surgery, Vol. 87, No. 1, pp. 69-76, January, 1980, discloses tests with a multi-chamber sequential pressure device. Optimal pressures were found to be 35 mmHg for the ankle, 30 mmHg for the calf, and 20 mmHg for the thigh, which produced a 140% increase in blood velocity, higher pressures did not cause any increase in blood velocity.

Salvian, et al., "Effects of intermittent pneumatic calf compression in normal and postphlebitic legs," J. Cardiovasc. Surgery, 29, 1988, pp. 37-41, evaluated two sequential compression devices and one single chamber device. Correct calf application was found to be critical in achieving an increase in blood velocity.

Most of the systems known for producing IPC are large, expensive, complex and uncomfortable for the patient. For example, in U.S. Patent 4,013,069, a system is disclosed that treats deep vein thrombosis in the thigh, the calf, and the ankle. This prior art system is accomplished with an elaborate system of multiple lines and mechanical valves and a multiplicity

of tubes leading from a complex control system to the air cells about the leg. The system also is complicated and apparently requires four timers, three pneumatic shift valves, and a separate tube from the controllers to each of the six pressure zones. It also requires means for intermittently initiating periodic deflation cycles at the end of inflation cycles. As will be seen, this is opposite to the system of the present invention, in which the pump operates continuously and the air cells exhaust automatically, at a rate great enough to permit rapid pressure drop.

There is a need for a device that provides graduated IPC and that is small, lightweight, economical to construct and operate, comfortable for the patient and efficient to use.

(3) OBJECTS OF THE INVENTION

The principal objective of the present invention is to provide a system for intermittent pneumatic compression that provides faster inflation, less complexity, lower cost, and greater patient comfort. These seemingly contradictory goals are achieved by employing unique strategies for the way in which the compressed air is accumulated and released to inflate the cuff; for the way compression is applied to the leg, and for the design of the cuff to facilitate inflation.

It is an object of the invention to provide a system for applying therapeutic intermittent pneumatic pressure to a limb, wherein said pressure is applied with rapid acceleration to effect therapeutic venous flow acceleration.

It is yet another object of the invention to provide a system for applying therapeutic intermittent pneumatic pressure to a limb, wherein said pressure is applied with more rapid acceleration than in prior art designs, to thereby effect therapeutic venous flow acceleration, and wherein said system is of relatively simple construction and relatively low cost.

It is yet another object of the invention to provide such a system for applying therapeutic intermittent pneumatic pressure to a limb, wherein said system affords greater patient comfort than prior art systems.

It is still another object of the invention to provide a system which provides graduated, sequential therapeutic intermittent pneumatic pressure to a limb.

Yet another object of the invention is to provide the entire system in a conveniently arranged carrying device which accommodates easy mobility and set up of the system.

Other objects, advantages, and novel features of the instant invention will be readily apparent to those skilled in the art from the following description and drawings.

DISCLOSURE OF THE INVENTION

In accordance with the simplest version of the invention, a system for applying therapeutic intermittent pressure to a limb is provided comprising a pump, a reservoir which receives pressurized air from the pump, an inflatable cuff for sequentially applying pressure to the limb, means for intermittently and quickly transmitting pressurized air from the reservoir to the inflatable cuff, and pressure relief means operatively coupled to the inflatable cuff for limiting the pressure therein. In operation, the pump operates substantially continuously to supply a steady flow of pressurized air to the reservoir. The means for intermittently transmitting pressurized air from the reservoir to the inflatable cuff comprises a valve operatively disposed between the reservoir and the cuff and a timer operatively coupled to the valve. The valve is normally in a closed position, so that pressurized air is allowed to build up in the reservoir to a level several times above that normally desired for therapeutic compression. The timer is set to open the valve to release pressurized air from the reservoir to the inflatable cuff at predetermined intervals and for a predetermined duration. This results in a very rapid pressurization of the inflatable cuff which in

turn leads to greater acceleration of venous flow, and thus more effective therapy to the affected limb. The valve preferably is a two way valve so that when closed to the reservoir it is open to atmosphere, allowing depressurization of the cuff.

In a preferred embodiment of the invention, the inflatable cuff is configured so as to apply pressure to the affected limb as efficiently as possible. Specifically, the cuff is configured to apply pressure to only the medial and lateral aspects of the limb, leaving open the anterior and posterior aspects, such that collateral (rather than circumferential) compression is achieved. In this preferred embodiment, the cuff comprises a pair of semirigid shells intended to be disposed along the medial and lateral aspects of the limb, with one or both of said shells being provided with one or more inflatable bladders along the inner surfaces thereof. The shells are secured around the injured limb such that when the valve is opened the bladders are pressurized and the semirigid shells resist such pressure, so that all the pressure is directed to the interior of the limb along the medial and lateral aspects thereof. One or more of the inflatable bladders is provided with an interior foam liner which partly fills the internal volume of the bladder(s) to promote rapid pressurization. The cuff of this preferred embodiment is also more comfortable for the

patient than prior art cuff devices which encompass the entire circumference of the affected limb.

In the preferred embodiment of the invention, the system may be made convenient and easy to use for the patient by mounting the pump, timer, valves and reservoirs within a convenient relatively rigid carrying case. This arrangement makes it simple for the system, including the inflatable cuff, to be transported and set up at the patient's comfort and convenience. In another version, a toroidal shaped reservoir has been found suitable for this purpose, although other shapes such as hollow boxes or cubes also may be used.

In the preferred embodiment of the invention, the system is configured to provide therapeutic intermittent pneumatic pressure to an affected limb, which pressure is applied in a graduated manner and/or sequentially along the limb, preferably from the distal end to the proximal end thereof. In this configuration, the system further comprises a second reservoir, and the cuff means is divided into first and second bladders, such that each of the first and second bladders is in fluid communication with the first and second reservoirs respectively, with the first bladder disposed along the distal region of the limb and said second bladder disposed along the proximal region thereof. In operation, the timer is set to open the first valve to transmit a pulse of pressurized air from

the first reservoir to the first bladder, and shortly thereafter the timer opens the second valve to transmit a pulse of pressurized air from the second reservoir to the second bladder, such that pressure is applied sequentially distally to proximally along the affected limb. The pressure achieved in the two bladders need not be equal. Typically, the pressure in the first (distal) bladder will be greater than the pressure in the second (proximal) bladder, such that graduated therapeutic IPC is achieved. By means of the system of the instant invention, the pressure rise in the first and second bladders is relatively rapid, such that the acceleration of venous flow is greater than in prior art devices and the therapeutic effect is thereby enhanced.

BRIEF DESCRIPTION OF THE DRAWINGS

Understanding of the detailed description of the invention will be enhanced by the accompanying figures, wherein like reference numerals indicate like parts, and wherein

FIG. 1 is a schematic representation of a simplified version of the system of the instant invention.

FIG. 2 illustrates a preferred embodiment of the cuff means of the instant invention.

FIG. 3 is a schematic representation of one embodiment of the invention wherein graduated sequential intermittent pressure is applied to a limb.

FIG. 4 is a schematic representation of a preferred embodiment of the invention wherein graduated and sequential intermittent pressure is applied to two limbs;

FIG. 5 illustrates a preferred arrangement for providing the system of FIG. 4 in a convenient case for transport and set up;

FIG. 6 is a perspective view of the carrying case of Fig. 5, in closed condition, showing other aspects of the invention; and

FIG. 7 is a perspective view of another embodiment of a reservoir and system of the instant invention.

BEST MODE FOR CARRYING OUT THE INVENTION

In the following description of the preferred embodiment of the instant invention, the system will be described in the configuration wherein therapeutic compression is provided to an affected limb for the minimization of risk of or prevention of DVT. It will be understood that the system is not necessarily so limited, and that it may be possible to adapt the system of the instant invention to other affected body

portions, and other than limbs and still remain within the scope and spirit of the invention.

As shown in Fig. 1, the simplified system of the prevent invention comprises a pump means 10 which is in fluid communication via tube 11 with a reservoir 20. The pump 10 is capable of operating on a substantially continuous basis to supply a steady flow of pressurized air to the reservoir 20. For economy and simplicity, the pump 10 is preferably small, inexpensive, and lightweight; a suitable type of pump is that which is commonly used to aerate a small aquarium, having a flow rate of about 1000-1500 cc/min and an output air pressure of about 200mm/hg, such as those manufactured by EIKO ELECTRIC of Taiwan.

The reservoir 20 may be made of any strong, inelastic air-impervious material; urethane film reinforced with nylon cloth is suitable. The reservoir 20 is in fluid communication via tube 22 and two-way valve 25 and tubes 28a and 28b with inflatable cuff means designated generally as 30, which means provides pressure directed to the interior of the limb.

The capacity of such pumps is of course far too small to inflate conventional cuffs in the few seconds necessary for effective performance. It is possible to overcome this limitation, and indeed provide faster inflation, by having pump 10 run continuously, not only during the brief period of

inflation, as in conventional systems, but also during the interval of a minute or so between pulses. During this interval, compressed air accumulates in reservoir 20, and rises to a pressure four or five times that appropriate for compression of the limb. When a timer 26 calls for inflation of cuff means 30, the two-way solenoid valve 25 is energized and compressed air flows quickly from reservoir 20 to cuff means 30. This relatively large volume of air at high pressure fills cuff 30 in about one second, but a fraction of the time required by conventional systems, even though pump 10 is small and inexpensive. While the air from reservoir 20 flows to cuff 30 at high pressure, the pressure in cuff 30 is limited to the desired level of 35 to 45 mm hg by a pressure relief valve 27.

The cuff means 30 may be in the form of a wrap-around cuff that compresses the limb circumferentially, as is known in the prior art, or, as part of the present invention, in the preferred embodiment, the cuff means 30 may be configured as two opposing cuff members schematically 31a and 31b, to apply pressure to only the medial and lateral aspects of the limb, leaving open the anterior and posterior aspects, and resulting in collateral compression.

While it is believed that collateral compression may be more effective in treating edema than circumferential pressure, applicants herein have found that, surprisingly, collateral compression is

more effective than circumferential compression for providing therapeutic compression to the deep veins of a limb in preventing DVT. In addition, the collateral compression cuff means is more comfortable to the user and more easily applied, so it is more likely to be used, and used correctly.

It has also been learned that where compression of the deep veins of the leg is required, efficient compression can be achieved where the cuff means 30 is configured to contact only the area of the calf, rather than the full length of the leg. This further reduces the volume of the cuff means 30 to be pressurized, and thus facilitates rapid pressurization, and also enhances patient comfort by reducing the area of skin covered by the cuff. In this preferred embodiment, the efficiency of the pressurization of the cuff means 30 is enhanced by reducing pre-inflation voids in the cuff means and by directing the pressurization inwardly toward the limb, while restricting outward expansion.

As shown in Fig. 2, the cuff means 30 preferably comprises a pair of cuff members 31a, 31b, each formed of semirigid shells 32a and 32b which may be molded of a durable thermoplastic material such as polypropylene, and are in the general shape of the medial and lateral aspects of the limb to which they are to be applied. In the case where the therapeutic pneumatic pressure is to be applied to the medial and

lateral aspects of the calf, then the shells 32a and 32b can be about 11 inches long, about 4 inches wide, and about 0.1 inches thick, and may taper toward the distal end for patient comfort.

As shown in Fig. 2, each semirigid shell 37a and 37b is provided on its interior surface with an inflatable bladder 33a and 33b, constructed in accordance with the disclosure of commonly assigned U.S. Patent No. 4,628,945, incorporated herein by reference. As shown in Fig. 2, each inflatable bladder may comprise two layers 34 and 35 of strong, fluid impervious plastic film. An appropriate material is 12 mil polyvinylchloride (pvc). Layers 34 and 35 are sealed to one another about their perimeter to form an inflatable bladder. Each bladder 33a and 33b is fitted with an inlet tube 28a and 28b respectively. In the preferred embodiment each bladder is provided with a thin layer of open cell foam material 36a and 36b. Foam layers 36a and 36b may be made, for example, of foamed polyurethane and may have a thickness of about 0.250-0.300 inches. Foam layers 36a and 36b facilitate the rapid pressurization of bladders 33a and 33b, as will be explained in more detail hereinafter.

The exterior of shells 32a and 32b are provided with a pair of straps 37, to secure the pair of cuff members 30a, 30b to the affected limb. The straps may be provided with mating hook and loop type

fastening means 38, 39, or other fastening means, preferably adjustable, as is known in the art.

In preferred embodiment, the straps 37 may be attached to a disposable sleeve of cloth-covered, air-impervious material (See FIG. 5) that slips over each shell structure. This permits the cuff means 30 to be reused, while providing a fresh, sterile, and economical cover thereof for each patient. This is a significant advantage over prior art systems which require that the entire cuff means be replaced for each patient.

When the cuff means 30 is properly secured by straps 37 to the affected limb, then the semirigid shells 32a and 32b resist outward expansion of the inflatable bladders 33a, 33b so that compression is efficiently directed inwardly toward the limb.

Referring again to Fig. 1, the simplest version of the system of the instant invention further comprises the two-way valve means 25 operatively disposed between the reservoir 20 and cuff means 30, the timer 26 operatively coupled to the valve means 25, and the pressure relief valve 27 operatively coupled to the cuff means 30. The valve means 25 may be a two-way solenoid valve as is known in the art. The timer 26 may be set to operate the valve means 25 at predetermined intervals and for predetermined periods of time, as hereinafter noted. When the valve normally

is "closed" it prevents communication between the reservoir 20 and cuff means 30, while simultaneously permitting air in the bladders 33a, 33b and in tubes 28a, 28b, to exhaust to atmosphere. When the valve 25 opens to the reservoir 20, it also closes communication of the bladders 33a and 33b to atmosphere.

In operation, the system of the instant invention provides pulsed, or intermittent, therapeutic pneumatic compression to an affected limb. The pump means 10 provides a steady flow of compressed air to the reservoir 20 which is of substantially greater volume than the bladders in cuff means 30. The pressure within the reservoir 20 is intended to reach a level of about four to five times that normally used for therapeutic compression. At predetermined intervals, the timer 26 energizes valve means 25, causing it to open for a predetermined duration, such that a pulse or sudden rush of pressurized air fills the bladders 33a and 33b of cuff means 30. The pressure relief valve 27 is of such size and capacity to prevent bladders 33a and 33b from becoming overpressurized. When the pulse is over, the valve means 25 is de-energized and returns to its closed condition, allowing the pressurized air in bladders 33a and 33b to bleed out through the two-way valve 25 at a desired rate such that bladders 33a and 33b return to ambient pressure.

The rapid rate of pressurization of the bladders has been shown to accelerate venous flow in the treated area. Rapid acceleration of venous flow has been shown to be therapeutic, particularly in the minimization or prevention of pooling or clotting of the blood in the deep veins. The greatly accelerated pressurization provided by the instant invention is highly advantageous over prior art pressurization systems which directly couple the pump means to the cuff means. In such prior art systems, the rate of pressurization is limited by the capacity of the pump and necessarily occurs relatively slowly, so that the rapid acceleration of venous flow as achieved by the present invention and the therapeutic advantages associated therewith, are not attained.

In accordance with the instant invention, the timer 26 may be set such that the valve means 25 is open for about three to five seconds, and at intervals of about sixty seconds. Studies have shown that this interval is required for the veins to refill with blood after being emptied by the short pulse of compression. The reservoir 20 should be sized relative to the cuff means 30 such that when the valve means 25 is opened, the cuff means 30 reaches the desired pressure level in about one second or less, preferably in about 0.5 seconds. The desired pressure level for the cuff means 30 will generally be about 35-55 mmHg above ambient. The pressure in the reservoir 20 just prior

to the opening of the valve means 25 may be about 180 mmHg or higher.

One of the bladders, 23b, may be provided at its proximal end with a sealed aircell 46 which is in fluid communication by means of tube 47 to a pressure level indicator provided by bellows 50.

The aircell 46 may be preinflated with a foam liner 49. If the cuff means 30 is properly applied to the affected limb, then the aircell 48 will be compressed slightly to cause a slight visible expansion of the bellows 50. This gives a visible indication that the cuff means 20 is on correctly but not too tight. Then, when the system is operating, each pressurization pulse causes full expansion of the bellows 50. The bellows 50 thus provides a visual indication that the system is applied and is functioning correctly to deliver therapeutic IPC to the affected limb. It will be seen that if the cuff means 20 is not properly applied to the affected limb, then the aircell 48 will not be compressed during a pressurization pulse, and the bellows 50 will not respond. This is a distinct advantage over prior art "indicators" which respond to internal system pressure, regardless of whether the cuff means is properly secured to the limb.

It will be appreciated that rapid pressurization of the bladders 33a and 33b is

important to the effectiveness of the therapeutic pressure provided by the instant invention. Such rapid pressurization is facilitated by reducing the amount of air required to inflate the cuff means 20. The foam layers 36a and 36b disposed within the bladders 33a and 33b have been found to reduce the pre-inflation voids within the bladders 33a and 33b and thus reduce the amount of air required to inflate them to the desired pressure, while still allowing the application of therapeutic pressure. In addition, if desired one of the bladders 33a or 33b may be preinflated to a desired pressure and permanently sealed. Then when the cuff means 30 is applied and used correctly, only the non-sealed bladder need be inflated to provide the desired intermittent application of pressure. Typically, the bladder for the lateral aspect of the limb will be pre-inflated and permanently sealed, and the bladder for the medial aspect will be cyclically inflated and deflated.

In an alternative preferred embodiment of the invention, the system may be designed to provide intermittent therapeutic pneumatic pressure to an affected limb in which pressure is graduated, or sequential, or both. It is known in the prior art to provide a sequential pressure system, wherein pressure is not applied to the entire affected area simultaneously. Rather, the pressure is applied in a sequential manner over the surface of the affected area of the body, preferably beginning at the distal region

and then progressing toward the proximal region. It is also known to apply graduated pressure to an affected area. In this mode of operation, unequal pressures are applied to the distal and proximal regions of the affected limb. Typically, greater pressure is applied to the distal region and less pressure is applied to the proximal region, to promote the flow of blood toward the heart.

The benefits of graduated and sequential intermittent pressure application are well-known in the art of therapeutic pressure devices for presenting DVT. In the past, however, devices capable of provided graduated and/or sequential intermittent therapeutic pneumatic pressure to a limb were large, cumbersome, uncomfortable, complex, and slow to inflate and therefore much less effective in accelerating blood flow.

Another embodiment of the system of the instant invention provides the rapid venous acceleration which gives improved therapy as described above, and also allows for such rapid acceleration to be applied in a graduated manner, or sequentially, or both. This embodiment is illustrated schematically in FIG. 3. As may be seen, the reservoir 120 may be divided by seals 121 into two compartments 120a and 120b. As shown, the pump means 110 has two outlets which are connected via tubes 111a and 111b to be in

fluid communication with the compartments 120a and 120b, respectively.

Each compartment 120a and 120b is provided with an outlet tube 122a and 122b, and a valve means 125a and 125b, respectively. The valves are connected by tubes 141a and 141b to a common manifold 140, which is provided with pressure relief valves 143a and 143b to prevent overpressurization thereof.

The bladders 133a and 133b of the cuff means are each divided into distal portions 145a and 145b and proximal portions 147a and 147b. The tubes 144a and 144b lead from the manifold 140 to the distal portions 145a, b, and the tubes 146a, b lead from the manifold 140 to the proximal portions 147a and 147b. At least one of the proximal portions 147a may have mounted thereon a sealed aircell 148. A tube 149 leads from the sealed aircell 148 to a bellows 150.

In operation, the pump means 110 is run continuously to provide a steady flow of air to the compartments 120a and 120b of the reservoir 120. For convenience, the pump means 110 can be a dual output pump, although the same effect can be achieved with a single output pump fitted with a y-connector to each of the reservoir compartments. The compartments preferably reach a pressure in the range of about 160-200 mmHg. After about sixty seconds, a timer (not shown) opens the valve means 125a, discharging

pressurized are from reservoir 120a and rapidly inflating the distal portions 145a and 145b of the bladders 133a and 133b. Generally about one second later or less, the timer opens the valve means 125b, discharging chamber 120b and rapidly inflating the proximal portions 147a and 147b of the bladders 133a and 133b. This delay in inflation of the proximal portions relative to the inflation of the distal portions produces the desired sequential IPC. The pressure relief valves 143a and 143b prevent over inflation of the distal portions 145a, b and proximal portions 147a, b respectively. The pressure relief valves 143a and 143b may also be set so that the pressure in the distal and proximal portions is not equal. Generally, the pressure in the distal portions will be greater than that in the proximal portions. The unequal pressures in the distal and proximal portions produce the desired graduated IPC. In particular, pressures of about 50 mmHg for the distal portion and about 40 mmHg for the proximal portion are preferred.

The sealed aircell 148 and the bellows 150 function together to indicate whether the cuff means 120 of the instant invention is being used and applied properly, as described above in connection with the aircell 48 and the bellows 50 of the embodiment of Figs. 1 and 2.

From the discussion above, it will be appreciated that this alternative embodiment of the invention may be even further simplified in its construction by preinflating and permanently sealing one of the bladders 133a or 133b. In such a construction, it would be necessary to have only a single tube leading from the manifold 140 to the distal portion 145, and only a single tube leading from the manifold 140 to the proximal portion 147.

In FIGS. 4-6 there is depicted the present preferred commercial embodiment employing the inventions of the present system. The schematic depicted in FIG. 4 is generally similar to that depicted in FIG. 3, except that the reservoir 320 comprises two separate components 320a and 320b, and there are two sets of cuff means 330A and 330B, one for each leg. A description of the schematic of FIG. 4 and the carrying case for the entire system follows, it being understood that operation of this system is generally similar to that for the system of FIG. 3, but includes graduated and sequential compression for two cuff means.

The pump 310 runs continuously. The air from its two output tubes 311, 312, comes together at cross connector 315. (If the pump had a single output, the cross connector 315 would be a Y). The output is then divided with one leg 316 going to reservoir 320a, the second leg 317 to reservoir 320b. In the line 316 to

reservoir 320a is a pressure relief valve 327 and a one way valve 328. Valve 327 controls the maximum pressure in the two reservoirs to about 170 mm hg, as desired.

Valve 328 passes air to reservoir 320a but blocks air to 320b. The valve 328 may be of the type disclosed and claimed in commonly assigned copending application Ser. No. 07/968,287, fild October 29, 1992, entitled: Automatic Fluid Circulation System and Method, the disclosure of which is incorporated herein by reference. This cross technique allows uniform pressure in the two reservoirs 320a,b even if the outputs from the two sides of the pump 310 are different. The one way valve 328 permits release of pressure from reservoir 320b without affecting the pressure in reservoir 320a.

After one minute of operation the reservoirs 320a, 320b are at the desired 170 mm pressure. Two-way solenoid valve 325b is energized by timer 326, releasing air from reservoir 320b through tube connectors 327 and Y connectors 328 in manifold 340, via tubes 344 to the four distal air bladder compartments (medial, lateral, left and right) of two cuff means 330A, 330B. Pressure relief value 343b limits the pressure to about 50 mm hg, as desired, and pressure in reservoir 320b falls of course to the same level. But the pressure in reservoir 320a remains at 170 mm, since outflow to reservoir 320b is blocked by one way valve 328. It should be noted the tube

connectors preferably are noted as male female and in reverse relationship to assure proper connection of the reservoirs to the distal and proximal compartments.

About .5 seconds later, the second solenoid 325a is energized by the timer 326, releasing air from reservoir 320a to the four proximal compartments 347. Valve 325a limits the proximal pressure to about 40 mm hg, as desired, and the pressure in reservoir 320a falls to the same 40 mm.

About 4.5 seconds later timer 326 deenergizes both solenoids 325a,b closing the passages to both reservoirs, and opening the passages from the cuff means 330A,B to atmosphere. Pressure in the distal and proximal compartments 345,347 falls to near zero. Pressure in reservoirs 320a and 320b rises over the next minute to 170 mm, and the cycle starts over.

Inflation of the proximal compartment compresses the pre-inflated pressure cell 348 only if the cuff means 330A is strapped onto a leg via straps 337. This causes expansion of the bellows 350, via tube 349, giving a visual indication that the system is working. If the cuff means is not on the leg, the cell 348 will not be compressed, even if the system is operating normally.

If desired the cuffs of course could have more than two compartments by adding reservoirs, solenoids, tubing and timed intervals.

The bladders in the versions depicted in FIGS. 3 and 4, which include distal and proximal compartments or portions, preferably are made in the manner disclosed in applicants commonly assigned U.S. Patent No. 5,125,400, of the general type depicted in FIGS. 11 or 16 thereof, in which the proximal aircell envelopes the distal compartment or portion, the disclosure of such patent being incorporated herein by reference. The advantage of such structure in the present invention in preventing DVT is the avoidance of any low pressure zone between the distal and proximal portions that may lead to a pooling of blood, as has been found to be the case in prior art DVT systems.

In FIGS. 5 and 6, a relatively rigid plastic shell-style carrying case 300 is provided for housing the entire system of FIG. 4, and for permitting easy portability thereof, and permitting easy mounting to a patient's bedside, if appropriate. A suitable electrical receptacle 301 is provided on one side wall 302 of the case 300, through which the appropriate electrical connections can be made by an appropriate extension cord (not shown).

As noted, illustrated in this embodiment is the system depicted in Fig. 4, which includes two

separate reservoirs, 320a and 320b, fed by the single pump 310 having the timing mechanism 336 incorporated therewithin, all provided in the case lower compartment 303. The upper compartment 304 of the case 300 (FIG. 4) permits storage of the two sets of cuff means 330A, 330B. One cuff means 330A is illustrated without a "cover" in the left hand portion of FIG. 5, and with a cover 305 and closed straps 337 in the right hand portion of FIG. 5. When disassembled for carrying, all of the necessary tubing is disconnected and the cuffs are stored in the upper compartment 304 of case 300.

As shown at the right hand side of the lower compartment 303, in right side wall 306 of case 300, there are the two valve connectors 327, one male and one female, to assure the mating connection to the proper tubes 344, 346 of the appropriate cuff members. Similarly, a connection 351 is provided for connection of the tube 349 to the bellows 250. As noted in FIG. 5, the bellows 350 is located directly in an upper wall 307 of the lower compartment 303 of the case 300 and is clearly visible during operation. An adjustable strap 308 is provided on the lower face portion 309, permitting the case 300 to be held directly on a bedside rail.

In this preferred embodiment, each reservoir 320a and 320b as made is approximately 18 inches long and five inches wide when deflated; each will inflate within the case 300 to a dimension of approximately 15

inches by 3 inches, having a capacity of approximately 50 cubic inches. The case 300 itself has overall dimensions of approximately 12" by 15" by 6".

In an alternate simplified embodiment as shown in Fig. 7, the reservoir 20 may be in the shape of a toroid or hollow square, and the pump means 10, valve means 25 and the timer 36 may all be mounted, such as on a support board, within the "hollow" portion of the toroid or hollow square. The reservoir 20 then serves to protect those components, and the entire system can be more compact and easier to set up and use. A looped strap 23 may be provided to hold the reservoir 20, such as from a hospital bed rail, not shown.

A system of the embodiments of Figs. 3 or 4 of the instant application may be operated to achieve an increase in blood flow in the femoral vein of about 250%, or more, substantially greater than the acceleration achieved by the devices of the prior art. A single chamber collateral compression or circumferential cuff like Fig. 1, can also achieve an increase in blood velocity of about 250% or more.

While much of the need is for treating venous flow in only the lower leg, it is common practice to treat the thigh as well with graduated pneumatic compression. Patent 4,013,069 discloses a typical system in which this is accomplished with an elaborate

inches by 3 inches, having a capacity of approximately 50 cubic inches. The case 300 itself has overall dimensions of approximately 12" by 15" by 6".

In an alternate simplified embodiment as shown in Fig. 7, the reservoir 20 may be in the shape of a toroid or hollow square, and the pump means 10, valve means 25 and the timer 36 may all be mounted, such as on a support board, within the "hollow" portion of the toroid or hollow square. The reservoir 20 then serves to protect those components, and the entire system can be more compact and easier to set up and use. A looped strap 23 may be provided to hold the reservoir 20, such as from a hospital bed rail, not shown.

A system of the embodiments of Figs. 3 or 4 of the instant application may be operated to achieve an increase in blood flow in the femoral vein of about 250%, or more, substantially greater than the acceleration achieved by the devices of the prior art. A single chamber collateral compression or circumferential cuff like Fig. 1, can also achieve an increase in blood velocity of about 250% or more.

While much of the need is for treating venous flow in only the lower leg, it is common practice to treat the thigh as well with graduated pneumatic compression. Patent 4,013,069 discloses a typical system in which this is accomplished with an elaborate

system of mechanical valves, and a multiplicity of tubes leading from the control system to the leg.

By the present invention, it will be understood that additional cuffs, for application to the thigh or to the foot if desired, may be provided, at but very modest increase in cost and with a minimization of additional valving, tubes and the like. Also, one or more pumps may be used if desired, but it is believed that the use of the dual reservoir system provided in FIG. 4, fed by a single pump, is the most efficient and economical. The use of the compact carrying case 300 also makes the unit highly mobile and convenient to use.

The foregoing detailed description of the specification and drawings and of the invention is given for clearness of understanding only, and no unnecessary limitations should be understood therefrom as modifications will be apparent to those skilled in the art and it is intended to cover in the following claims all such modifications.

CLAIMS

1. An apparatus for applying therapeutic intermittent pressure to a body portion, said apparatus comprising

a pump means,

a fluid reservoir for receiving a substantially steady flow of pressurized fluid from said pump means,

inflatable cuff means for applying pressure to said body portion, said cuff means being in fluid communication with said reservoir,

means for facilitating the intermittent transmission of compressed fluid from said reservoir to said inflatable cuff means,

pressure relief means operatively coupled to said inflatable cuff means for controlling the pressure therein; and means permitting exhaustion of fluid from said cuff means.

2. The apparatus of claim 1 wherein said means for facilitating the intermittent transmission of compressed fluid comprises a valve means operatively disposed between said reservoir and said cuff means and a timer operatively coupled to said valve means, whereby said timer may be set to operate said valve at predetermined intervals and for pre-determined periods of time to control the intermittent transmission of compressed air from said reservoir to said cuff means.

3. The apparatus of claim 2 wherein said reservoir and said cuff means are so sized and dimensioned relative to one another such that said cuff means can be inflated to an optimum pressure at a rate sufficient to effect therapeutic venous flow acceleration.

4. The apparatus of claim 3 wherein said cuff means can be inflated to an optimum pressure in about one second or less.

5. The apparatus of claim 3 wherein said optimum pressure of said cuff means is about 35-55 mmHg above atmospheric.

6. The apparatus of claim 3 wherein said timer is set to operate said valve means at approximately one-minute intervals.

7. The apparatus of claim 1 wherein said cuff means is adapted to apply said therapeutic pressure substantially around the circumference of said body portion.

8. The apparatus of claim 1 wherein said cuff means is adapted to apply said therapeutic pressure substantially to the medial and lateral aspects of said body portion.

9. The apparatus of claim 8 wherein said cuff means comprises at least a first inflatable bladder adapted to be disposed along either the medial or lateral aspect of said body portion.

10. The apparatus of claim 9 further comprising a piece of open cell foam disposed within said first inflatable bladder.

11. The apparatus of claim 9 wherein said cuff means further comprises a sealed, pre-inflated bladder disposed in opposition to said first inflatable bladder.

12. The apparatus of claim 9 wherein said cuff means further comprises a second inflatable bladder disposed in opposition to said first inflatable bladder.

13. The apparatus of claim 12 further comprising a piece of open cell foam disposed within said second inflatable bladder.

14. The apparatus of claim 9 wherein said cuff means further comprises a rigid shell fixed to said first inflatable bladder such that said bladder is disposed between said body portion and said rigid shell when said cuff means is applied to said body portion.

15. The apparatus of claim 14 wherein said cuff means further comprises means for fastening said cuff means to said body portion.

16. The apparatus of claim 15 wherein said fastening means is affixed to said rigid shell.

17. The apparatus of claim 15 further including a sleeve which fits over a bladder of said cuff means and to which said fastening means is affixed.

18. The apparatus of claim 1 wherein said cuff means includes a distal portion and a proximal portion, and wherein said reservoir includes a first portion in fluid communication with said distal portion of said cuff means and a second portion in fluid communication with said proximal portion of said cuff means.

19. The apparatus of claim 18 wherein said distal portion and said proximal portion of said cuff means are pressurizable at different times, so as to provide sequential therapeutic pressure to said body portion.

20. The apparatus of claim 18 wherein said distal portion and said proximal portion of said cuff means are pressurizable to different pressures, so as

to provide graduated therapeutic pressure to said body portion.

21. The apparatus of claim 1 further including an air cell adapted to be operatively disposed between said cuff means and said body portion, and a bellows in sealed fluid communication with said air cell, said air cell and bellows adapted to provide an indication of the intermittent application of therapeutic pressure to said body portion.

22. The apparatus of claim 2 wherein said means permitting exhaustion of fluid from said cuff means also comprises said valve means.

23. A method for promoting accelerated venous blood flow in a body portion, said method comprising;

providing a pressurized air reservoir which receives a substantially steady flow of pressurized air from an air pump;

providing a cuff means for receiving said pressurized air, said cuff means being in operative contact with said body portion;

cyclically repeating a pulsing sequence, said sequence comprising (a) transmitting a pulse of pressurized air from said reservoir to said cuff means, such that said cuff means reaches an optimum pressure in about one second or less, thereby causing venous

blood to flow in said body portion at an accelerated rate, (b) maintaining said receiving means at about said optimum pressure for a pre-determined duration, and (c) allowing a pre-determined interval before transmission of the next pulse, during which interval the pressure in the receiving means can return to about ambient and the velocity of the venous blood flow in said body portion is reduced from its accelerated rate.

24. The method of claim 23 wherein said cuff means is in operative circumferential contact with said body portion.

25. The method of claim 24 wherein said cuff means is in operative non-circumferential contact with said body portion.

26. The method of claim 25 wherein said body portion is a leg and said means for receiving said pressurized air is in operative contact with portions of the medial and lateral aspects of said leg.

27. The method of claim 22 wherein said optimum pressure in said cuff means is about 35-55 mmHg.

28. The method of claim 26 wherein said pre-determined interval between pulses is about 60 seconds.

29. The method of claim 27 wherein said predetermined duration of each pulse is about 3-10 seconds.

30. The method of claim 27 wherein said means includes a distal portion and a proximal portion, and wherein said pressurized air is transmitted to each said portion.

31. The method of claim 29 wherein said pressurized air is transmitted first to said distal portion and then to said proximal portion to provide sequential pressurization to said body portion.

32. The method of claim 30 wherein the pressure in said distal portion is greater than the pressure in said proximal portion to provide graduated pressurization to said body portion.

33. An apparatus for applying therapeutic intermittent pressure to a body portion, said apparatus comprising

a single pump means;

first and second air reservoirs, each in fluid communication with said pump means so as to receive a substantially steady flow of pressurized air therefrom;

at least one inflatable cuff means adapted to be in operative contact with said body portion, said cuff means having a distal portion in fluid

communication with said first reservoir and a proximate portion in fluid communication with said second reservoir; and

means for intermittently releasing a pulse of air from said first reservoir to inflate said distal portion, and for intermittently releasing a pulse of air from said second reservoir to inflate said proximal portion, whereby the pressure of said air pulses is transmitted via said distal and proximal portions to said body portion to effectively accelerate the venous flow therein.

34. The apparatus of claim 32 wherein said means for intermittently releasing pulses of air comprise a first two-way solenoid valve operatively disposed between said first reservoir and said distal portion, a second two-way solenoid valve operatively disposed between said second reservoir and said proximal portion, and a timer operatively coupled to said first valve and said second valve, such that said timer can cause each of said valve means to open at pre-determined intervals and to remain open for a pre-determined duration, to provide intermittent pressurization of said distal and proximal portions.

35. The apparatus of claim 33 further indicating a second inflatable cuff means adapted to be in operative contact with another body portion, said second cuff means having a distal portion coupled in fluid communication by said first valve to said first reservoir, and a proximal portion coupled in fluid

communication by said second valve to said second reservoir, such that said apparatus can apply intermittent pressure to said first cuff means and said second cuff means to effectively accelerate venous flow in said first body portion and said second body portion.

36. The apparatus of claim 34 further including a visual indicator means, said indicator means comprising an air cell mounted on said cuff means and in closed fluid communication with a bellows, such that when said cuff means are pressurized, pressure will be transmitted to said air cell and to said bellows, such that said bellows will perceptibly respond to said pressure to provide a visual indication of said pressurization.

37. The apparatus of claim 35 further including a portable carrying case, said case adapted to fixedly contain said first reservoir, second reservoir, pump means, timer, first valve, and second valve; and adapted to contain said cuff means, such that said cuff means can be removed while maintaining said cuff means in fluid communication with said first and second reservoirs; such that said apparatus may be readily transported for convenience.

38. The apparatus of claim 36 wherein said carrying case is semi-rigid and closable, and has a connector for a power supply mounted through a wall

HEALTH CARE PROXY

I, ELIZABETH G. REILINGER, of Boston Massachusetts, pursuant to the provisions of chapter 201D of the General Laws of Massachusetts, appoint my son, GEOFFREY LEWIS REILINGER, as my health care agent.

If he is not available, willing or competent to serve and is not expected to become available, willing and competent to make a timely decision given my medical circumstances, I appoint my friend, JOHN SIMMONS, as my alternate health care agent.

My health care agent shall have authority to make health care decisions on my behalf if it is determined pursuant to section 6 of said chapter 201D that I lack the capacity to make or to communicate health care decisions and in making such decisions I request that my wishes as expressed in the statement attached hereto be respected.

Date:

We, the witnesses, each affirm that the said ELIZABETH G. REILINGER, signed this instrument in our presence, and that he appeared to be at least 18 years of age, of sound mind and under no constraint or undue influence.

Witness	Address
Witness	Address

thereof, and fluid communication means mounted in a wall thereof for connecting said cuff means to said valve, such that said apparatus can be operated when said cuff means are removed from said case and said case is closed.

39. The apparatus of claim 37 wherein said bellows is mounted through a wall of said carrying case, such that said visual indication may be seen when such case is closed.

40. The apparatus of claim 32, wherein said distal and proximal portions of said inflatable cuff means are arranged to prevent any discontinuity in pressurization of the associated body portion between said distal and proximal portions of said cuff means, thereby reducing the likelihood of pooling of blood in the area between the distal and proximal portions.

AMENDED CLAIMS
[received by the International Bureau on 6 December 1994 (06.12.94); original claims 1-40 replaced by amended claims 1-25 (8 pages)]

1. An apparatus for applying therapeutic intermittent pressure to a human leg, said apparatus comprising

pump means,

inflatable cuff means for applying pressure to the leg, said cuff means being in fluid communication with said pump means, said cuff means being inflatable to an optimum pressure in less than about one second, and said cuff means being configured to apply said therapeutic pressure substantially to the medial and lateral aspects of the leg,

means for facilitating the intermittent transmission of compressed fluid from said pump means to said inflatable cuff means, said facilitating means comprising a valve means operatively disposed between said pump means and said cuff means and a timer operatively coupled to said valve means, whereby said timer may be set to operate said valve means at predetermined intervals and for pre-determined periods of time to control the intermittent transmission of compressed fluid from said pump means to said cuff means, said valve means also permitting exhaustion of fluid from said cuff means,

pressure relief means operatively coupled to said inflatable cuff means for controlling the pressure therein.

2. The apparatus of claim 1 wherein said cuff means comprises at least a first inflatable bladder adapted to be disposed along either the medial or lateral aspects of the leg.

3. The apparatus of claim 2 further comprising a piece of open cell foam disposed within said first inflatable bladder.

4. The apparatus of claim 2 wherein said cuff means further comprises a sealed, pre-inflated bladder disposed in opposition to said first inflatable bladder.

5. The apparatus of claim 2 wherein said cuff means further comprises a second inflatable bladder disposed in opposition to said first inflatable bladder.

6. The apparatus of claim 5 further comprising a piece of open cell foam disposed within said second inflatable bladder.

7. The apparatus of claim 2 wherein said cuff means further comprises a rigid shell fixed to said first inflatable bladder such that during use said bladder is disposed between the leg and said rigid shell.

8. The apparatus of claim 7 wherein said cuff means further comprises means for fastening said cuff means to the leg.

9. The apparatus of claim 8 wherein said fastening means is affixed to said rigid shell.

10. The apparatus of claim 8 further including a sleeve which fits over a bladder and an affixed shell of said cuff means and to which said fastening means is affixed.

11. The apparatus of claim 18 wherein said means for intermittently releasing the pulses of air from said first and second reservoirs is capable of releasing said pulses of air at different times to cause said distal portion and said proximal portion of said cuff means to be pressurized at different times, so as to provide sequential therapeutic pressure to the leg.

12. The apparatus of claim 18 wherein said distal portion and said proximal portion of said cuff means are pressurizable to different pressures, so as to provide graduated therapeutic pressure to said body portion.

13. The apparatus of claim 1 further including an air cell adapted to be operatively disposed between said cuff means and the leg, and a bellows in sealed fluid communication with said air

cell, said air cell and bellows adapted to provide an indication of the intermittent application of therapeutic pressure to said body portion.

14. A method for promoting accelerated venous blood flow in a human leg, said method comprising;

providing at least two pressurized air reservoirs which receive a substantially steady flow of pressurized air from a single air pump;

providing a cuff means for receiving said pressurized air, said cuff means being in operative contact with the associated leg and having a distal portion in fluid communication with a first reservoir and a proximal portion in fluid communication with a second reservoir;

cyclically releasing an intermittent pulse of air from said first reservoir to inflate said distal portion at one pressure, and releasing an intermittent pulse of air from said second reservoir to inflate said proximal portion at a lesser pressure, whereby the pressure of said air pulses is transmitted via said distal and proximal portions to the leg to effectively accelerate the venous flow therein;

and providing a valve means for maintaining the pressure in said second reservoir during the release of said pulse of air from said first reservoir.

15. The method of claim 14 wherein said cuff means is in operative contact with portions of the medial and lateral aspects of the leg.

16. The method of claim 14 wherein said pressurized air is transmitted first to said distal portion and then to said proximal portion to provide sequential pressurization to the leg.

17. The method of claim 16 wherein the pressure in said distal portion is greater than the pressure in said proximal portion to provide graduated pressurization to the leg.

18. An apparatus for applying therapeutic intermittent pressure to a human leg, said apparatus comprising

a single pump means;

first and second air reservoirs, each in fluid communication with said pump means so as to receive a substantially steady flow of pressurized air therefrom;

at least one inflatable cuff means adapted to be in operative contact with the leg, said cuff means having a distal portion in fluid communication with said first reservoir and a proximal portion in fluid communication with said second reservoir;

means for intermittently releasing a pulse of air from said first reservoir to inflate said distal portion at one pressure, and for intermittently releasing a pulse of air from said second reservoir to inflate said proximal portion at a lesser pressure, whereby the pressure of said air pulses is transmitted via said distal and proximal portions to the leg to effectively accelerate the venous flow therein, said

intermittent release means being capable of maintaining the pressure in said second reservoir during the release of said pulse of air from said first reservoir.

19. The apparatus of claim 18 wherein said means for intermittently releasing pulses of air comprise a first two-way solenoid valve operatively disposed between said first reservoir and said distal portion, a second two-way solenoid valve operatively disposed between said second reservoir and said proximal portion, and a timer operatively coupled to said first solenoid valve and said second solenoid valve, such that said timer can cause each of said solenoid valves to open at pre-determined intervals and to remain open for a pre-determined duration, to provide intermittent pressurization of said distal and proximal portions.

20. The apparatus of claim 19 further comprising a second inflatable cuff means adapted to be in operative contact with a second leg, said second cuff means having a distal portion coupled in fluid communication by said first solenoid valve to said first reservoir, and a proximal portion coupled in fluid communication by said second solenoid valve to said second reservoir, such that said apparatus can apply intermittent pressure to said first cuff means and said second cuff means to effectively accelerate venous flow in the first leg portion and the second leg.

21. The apparatus of claim 19 further including a visual indicator means, said indicator means comprising an air cell mounted on said cuff means and in closed fluid communication with a bellows, such that when said cuff means are pressurized, pressure will be transmitted to said air cell and to said bellows, such that said bellows will perceptibly respond to said pressure to provide a visual indication of said pressurization.

22. The apparatus of claim 21 further including a portable carrying case, said case adapted to fixedly contain said first reservoir, second reservoir, pump means, timer, first valve, and second valve; and adapted to contain said cuff means, such that said cuff means can be removed while maintaining said cuff means in fluid communication with said first and second reservoirs; such that said apparatus may be readily transported for convenience.

23. The apparatus of claim 22 wherein said carrying case is semi-rigid and closable, and has a connector for a power supply mounted through a wall thereof, and fluid communication means mounted in a wall thereof for connecting said cuff means to said first and second valves, such that said apparatus can be operated when said cuff means are removed from said case and said case is closed.

24. The apparatus of claim 23 wherein said bellows is mounted through a wall of said carrying case, such that said visual indication may be seen when such case is closed.

25. The apparatus of claim 18, wherein said distal and proximal portions of said inflatable cuff means are substantially adjacent one another to prevent any discontinuity in pressurization of the associated leg between said distal and proximal portions of said cuff means, thereby reducing the likelihood of pooling of blood in the area between the distal and proximal portions.

Fig. 1

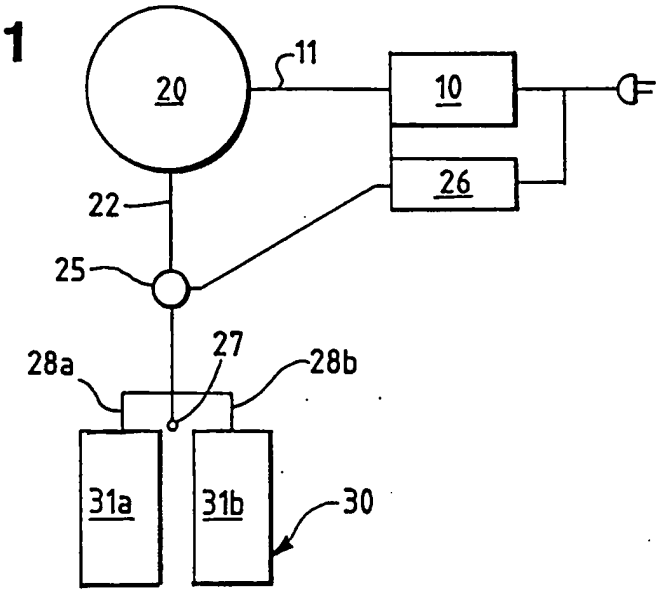

20
11
10
26
22
25
27
28a
28b
31a
31b
30

Fig. 2

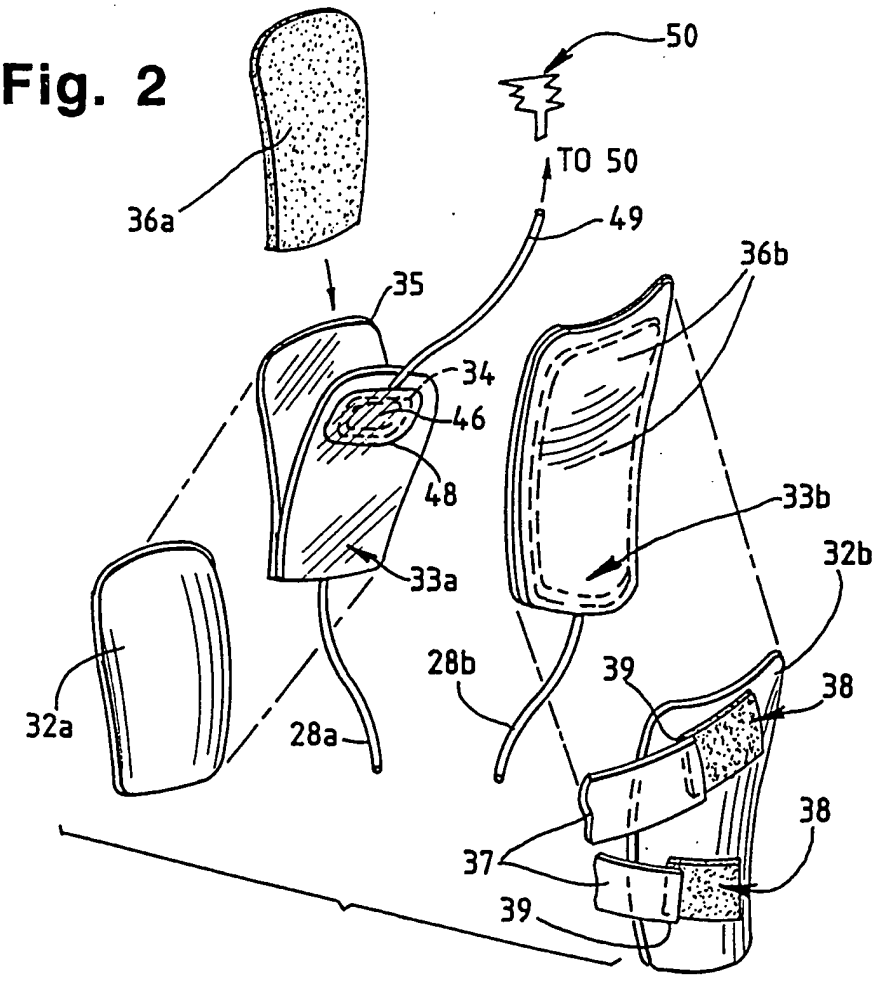
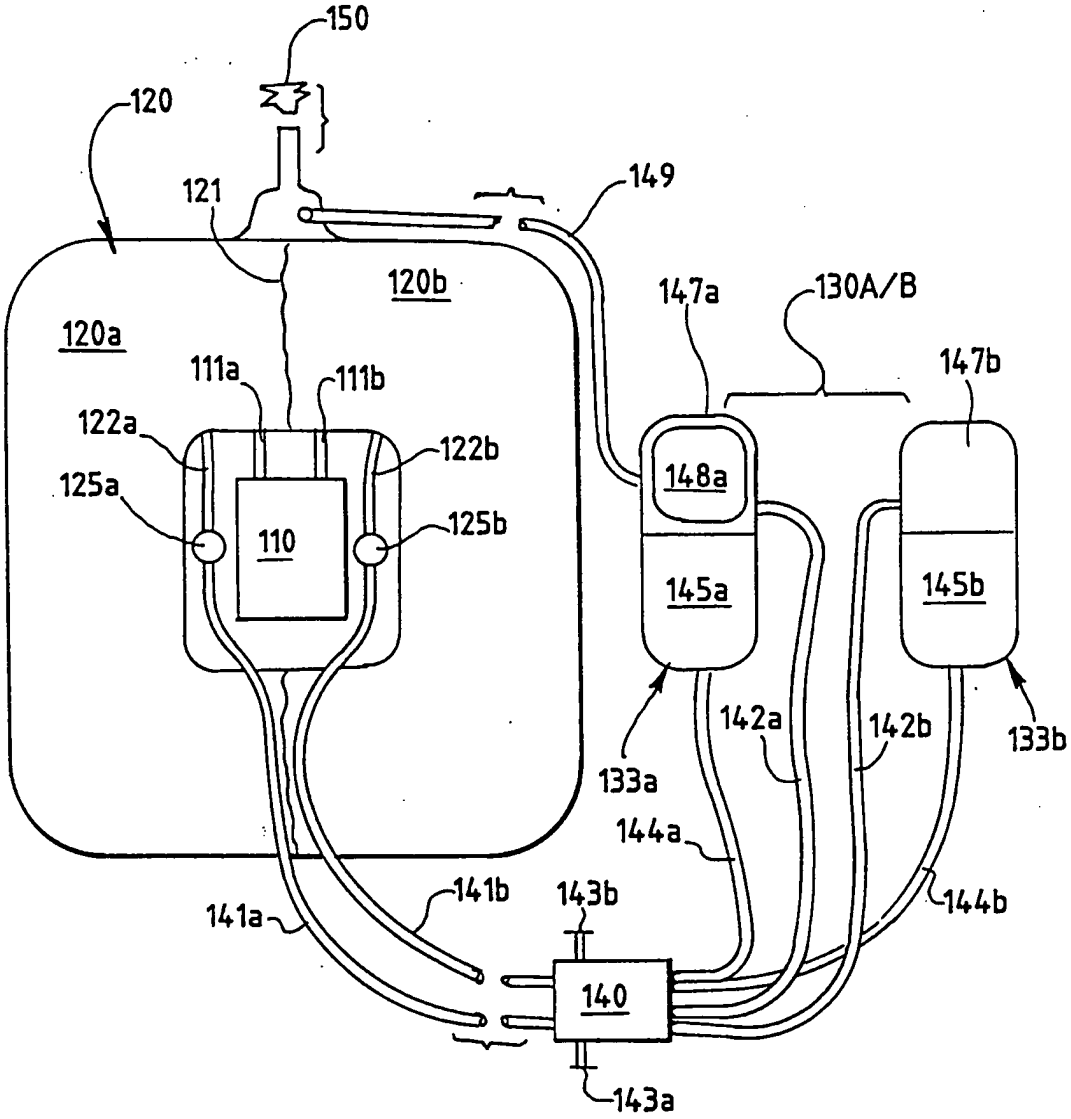

50
TO 50
36a
49
36b
35
34
46
48
33b
32b
33a
28b
39
38
32a
28a
38
37
39

Fig. 3


150
120
121
149
120b
147a
130A/B
147b
120a
111a
111b
122a
122b
125a
125b
110
148a
145a
145b
133a
142a
142b
133b
144a
144b
141a
141b
143b
140
143a

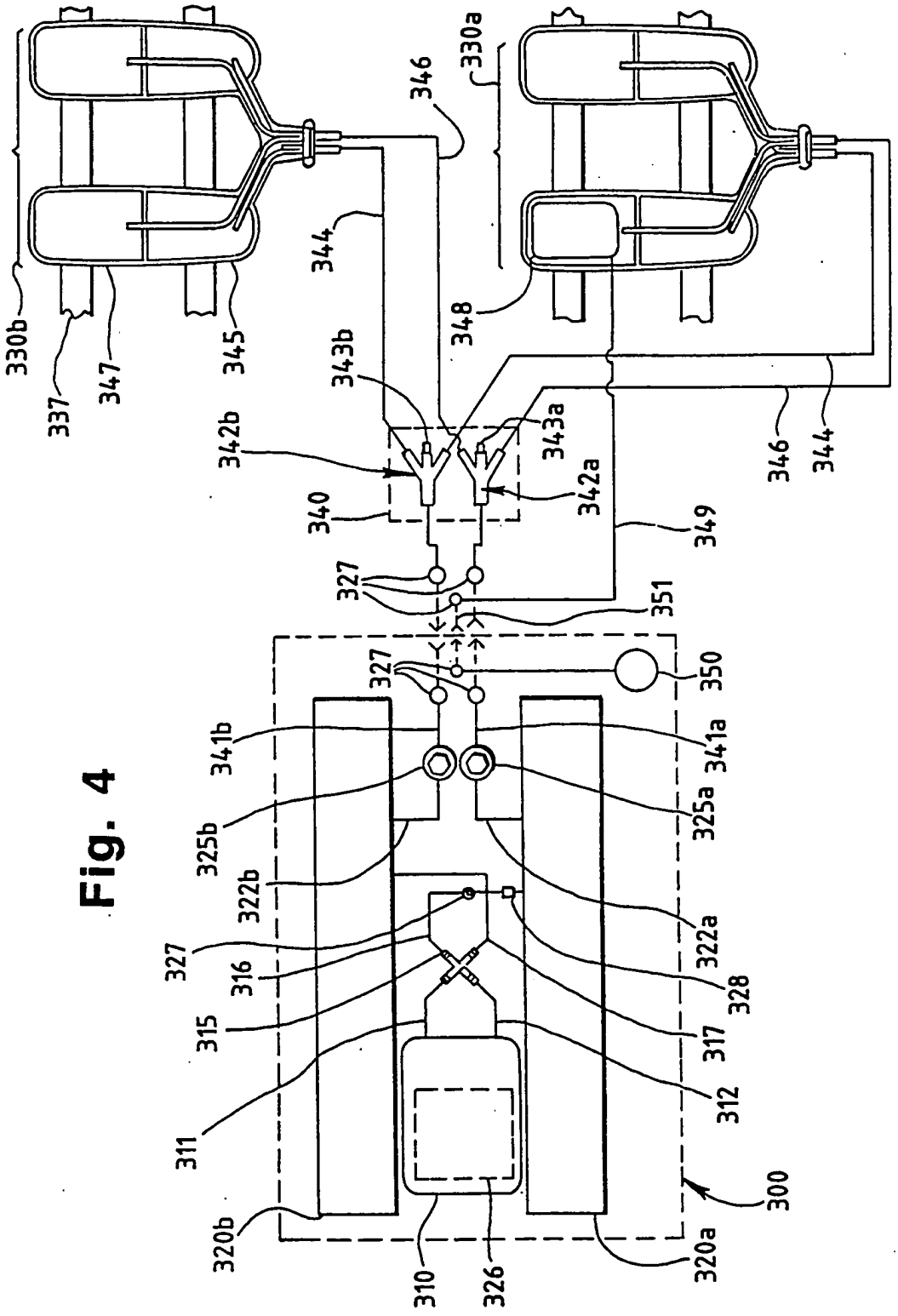
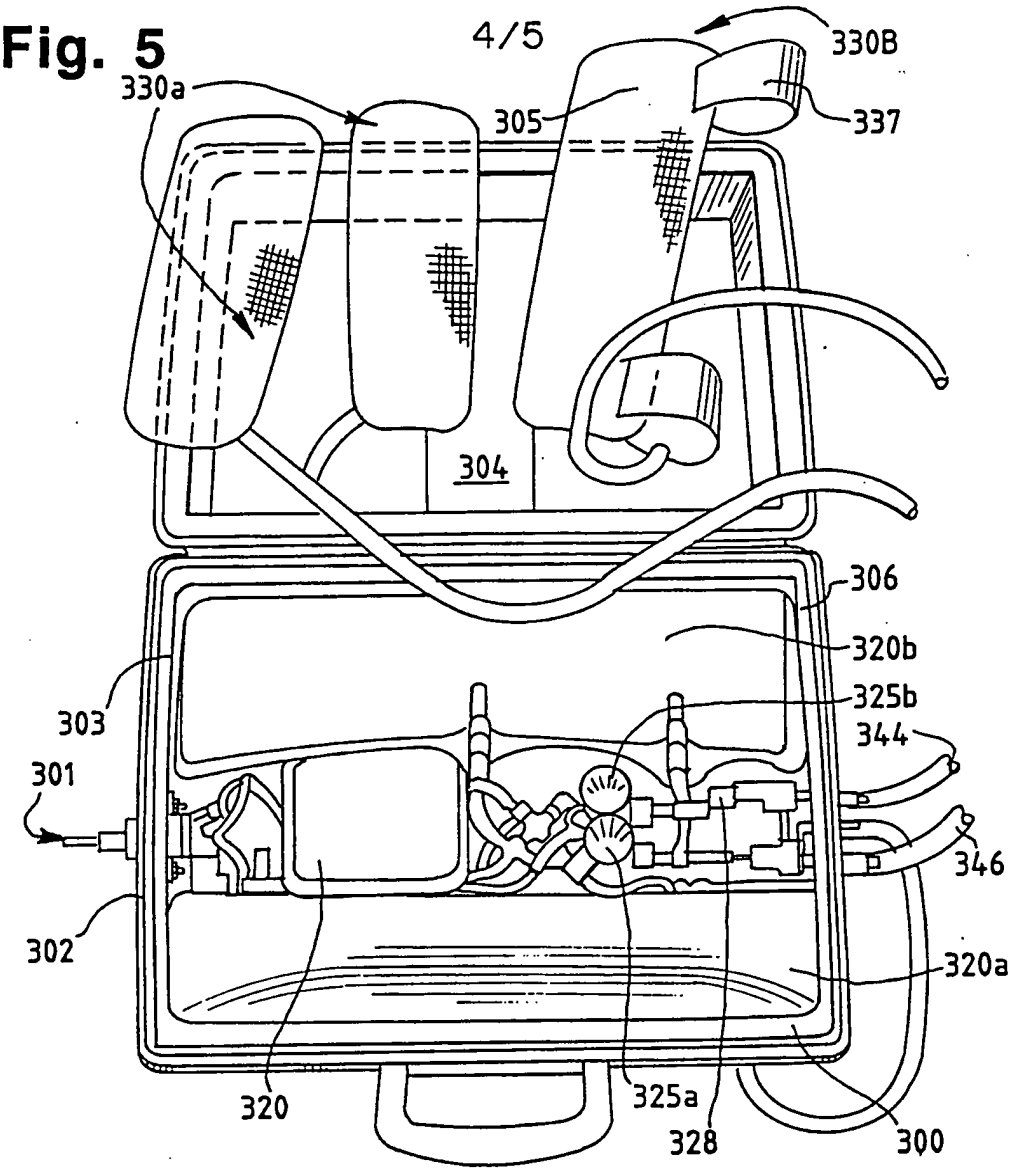

330b
337
347
345
344
346
330a
348
343b
343a
342b
342a
340
349
327
351
350
341b
341a
325b
325a
322b
322a
316
328
315
317
311
312
320b
320a
310
326
300

Fig. 4

Fig. 5


330B
330a
305
337
304
306
320b
325b
303
344
301
346
302
320a
320
325a
328
300

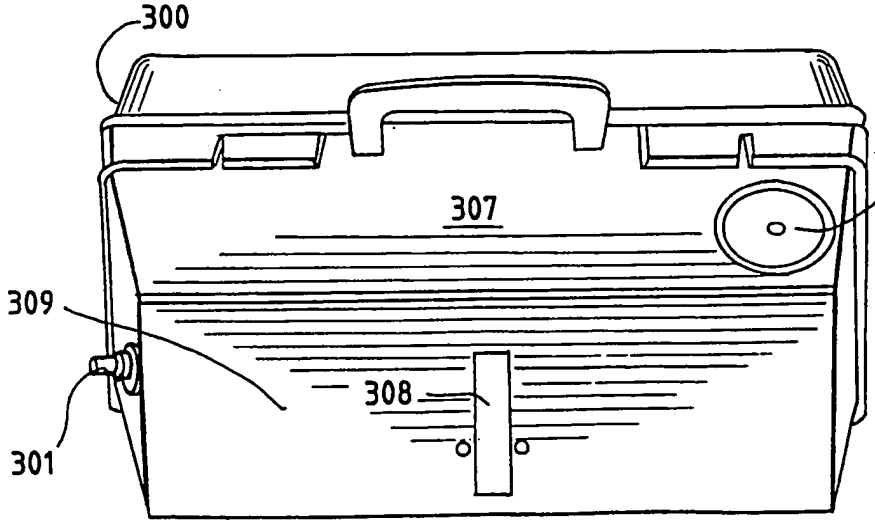
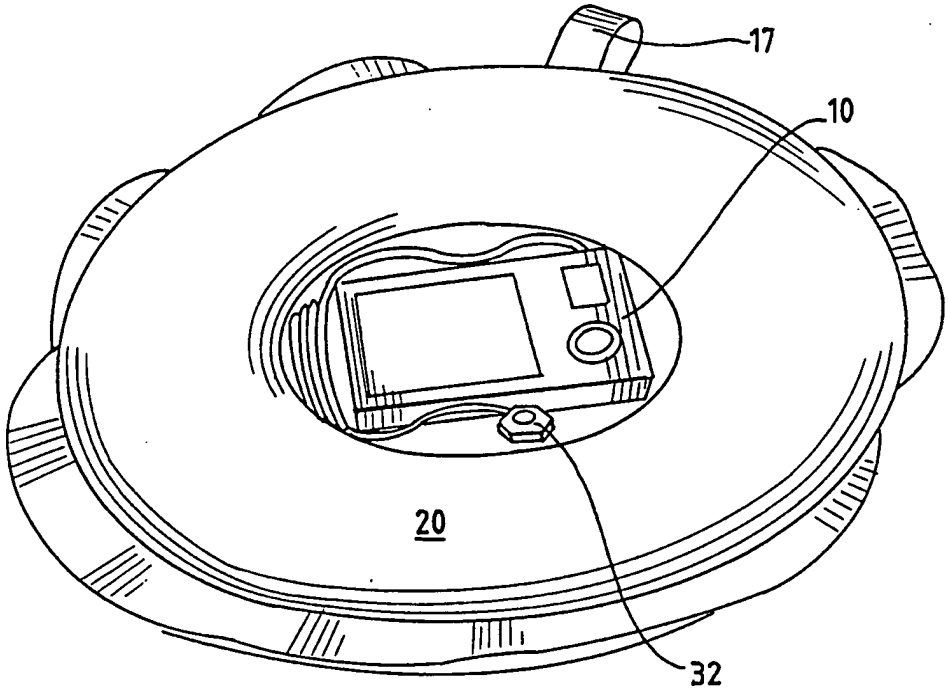

300
350
307
309
308
301

Fig. 6

Fig. 7



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/07577

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61H 9/00
US CL :601/152
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 128/DIG 20; 601/148-152; 602/13

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
APSS Search Terms: circulation, endema, thrombosis, inflatable, pneumatic, rigid shell or cast, bellow, indicator

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,370,975, (WRIGHT), 01 February 1983. See column 2, lines 8-11.	1-10, 12-20, 22-35, 40
Y	US, A, 3,826,249, (LEE ET AL.), 30 July 1974. See column 5, lines 35-55.	1-10, 12-20, 22-35, 40
Y	US, A, 3,901,221, (NICHOLSON ET AL.), 26 August 1975. See column 1, lines 50-55.	4-6, 23-3 2
Y	US, A, 4,628,945, (JOHNSON, JR.), 16 December 1986. See column 3, line 50 - column 4, line 50.	10, 12, 13
Y	US, A, 3,892,229, (TAYLOR ET AL.), 01 July 1975. See Fig. 1.	35
Y	US, A, 5,218,954, (VAN BEMELEN), 15 June 1993. See column 1, lines 37-39.	14-17

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
17 AUGUST 1994

Date of mailing of the international search report
OCT 06 1994

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer
JEANNE MOLLO
Telephone No. (703) 308-0063

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/07577

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Cardiovascular Research, Volume XX, NO. 8, pp. 588-596, August 1986, ROGER KAMM ET AL., OPTIMASATION OF INDICES OF EXTERNAL PNEUMATIC COMPRESSION FOR PROPHYLAXIS AGAINST DEEP VEIN THROMBOSIS: RADIONUCLIDE GATED IMAGING STUDIES.	4, 23-32
Y	Athletic Training, JNATA, Volume 26--Fall 1991, GARY B. WILDERSON, EdD, ATC, Treatment of the Inversion Ankle Sprain Through Synchronous Application of Focal Compression and Cold. See especially page 222.	8-10, 12, 13